PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200301025WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/DK2004/000822	International filing date *(day/month/year)* 26.11.2004	Priority date *(day/month/year)* 28.11.2003

International Patent Classification (IPC) or national classification and IPC
C12N15/82, A01N65/00, C07K16/16

Applicant
UNIVERSITY OF COPENHAGEN

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.09.2005	02.12.2005

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000822

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-53 as originally filed

Sequence listings part of the description, Pages

1-18 as originally filed

Claims, Numbers

1-26 as originally filed

Drawings, Sheets

1/10-10/10 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000822

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 19-22

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 19-22

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000822

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	23,25
	No:	Claims	1-18,24,26
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-18,23-26
Industrial applicability (IA)	Yes:	Claims	1-18,23-26
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment on

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional observations, if necessary:

1 The following documents are relevant, the numbering will be maintained

D1: EP1033405.
D2: WO0141556.
D3: The Plant Journal 32:975-983, 2002.
D4: bk3western03.pdf, July 1, 2003.
D5: Trends in Plant Science 6(9):392-394, 2001.

Re Item I
Basis of the report

2 **Essentially Biological Process**

2.1 Claims 15,17, and 25 extend to methods within the meaning of Rule 67.1(ii) PCT.

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

3 The ISA found that the application lacked unity of invention and invited the applicant to pay an additional search fee in accordance with Article 17(3)(a) and Rule 40.1 PCT. The applicant elected not to pay this fee. The International Search Report has therefore only been established for the subject matter of claims 1-18, and 23-26. The subject matter of claims 19-22 has not been searched and has therefore not been examined in accordance with Article 17(2)(a) or (3) and Rule 66.1(e) PCT.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject matter under examination is that defined by claims 1-18, and 23-26 (cf. section III)

4 **Novelty**

4.1 The subject matter of claims 1-18,24 and 26 is not new within the meaning of Article 33(2) PCT for the following reasons.

4.2 D1(cf. SEQ ID NOS:49381 and 49382 encoded by 49380) discloses a sequence identical with SEQ ID NO:2 i.e a MKS1 polypeptide. It also claims transgenic plants comprising this sequence(cf. claims).Consequently enhanced disease resistance is an inherent property of these plants. Methods and vectors for producing the transgenic plants is also implicitly disclosed. This subject matter is directly and unambiguously derivable from said disclosure and therefore can not be seen as a selection invention. The subject matter of claims 1,15,18,24 and 26 is therefore not new.

4.2.1 The subject matter of claims 2-14,16, and 17 does not add new subject matter over that of the claims mentioned in 5.2 as the claimed combination of features is also directly and unambiguously derivable from D1.

5 **Inventive Step**

5.1 The requirements of Article 33(3) PCT are not fulfilled, as even if novelty could be established for the subject matter underlying claims 1-18, and 23-26, it would lack an inventive step for the following reasons.

5.2 The closest state of the art is D4. It discloses transgenic plants overexpressing the substrate of MPK4 having enhanced disease resistance. The disclosure is not enabling in that MKS1 is not made available. The subject matter of the application differs from that of D4 in that it identifies the substrate MKS1. The problem underlying the application is the implementation of the concept made available in D4. In view of the need to develop effective disease resistance in plants there is an incentive from D4 to reduce the teaching thereof to practice. D5 is in the field of disease resistance in relation to MPK4 and discloses the means by which to identify the substrate (MKS1). The skilled person would be aware of this teaching. Since the application of this teaching provides the skilled person with a reasonable expectation of solving the problem, the claimed subject matter would be arrived at in an obvious manner devoid

of inventive skill or ability.

5.3 The reasonable expectations of the skilled person are directed to the success of solving the above-mentioned problem. D5 in combination with the common general knowledge of the skilled person clearly provides a technical teaching suitable for identifying MPK4 interactors such as MKS1. Not only does it disclose one potential target as a transcription factor it also direct itself to another target that controls SA response and therefore can not be considered as totally divergent from the teaching of D4. Notwithstanding this it is the teaching of D4 that is the starting point of the present problem and determines the direction the skilled person would follow. In this respect starting from D4 the disclosure D5 indicates that two hybrid screening has been successful in identifying other MPK4 interactors. Hence the skilled person would not be deterred from seeing this method as routine and applying it to the isolation of MKS1. The skilled person would also be capable of generating suitable bait sequences of MPK4 without exercising any undue burden. Even if the process of screening the interactors would be time consuming the skilled person would not need to be aware of MAP kinase or transcription factor interacting domains to screen for MKS1 since the activity of this protein in transgenic assays is known from D4. Hence it involves nothing more than routine experimentation to arrive at the MKS1 of D4 given the teaching of D5.

Re Item VIII

Certain observations on the international application

6 **Clarity**

6.1 In order to expedite the procedure the division notes the following deficiencies arising from the requirements of Article 6 PCT.

6.2 It is not clear if **MAP kinase substrate** refers to a MAP kinase that is a substrate, or to a substrate for a MAP kinase. In the latter case this does not appear to be limited to a substrate of MPK4. However the application is only directed to substrates of this kinase. This inconsistency leads to a lack of clarity and an absence of the essential technical features. The term **MKS1** is a laboratory designation without any technical

meaning. It is not evident from the claim alone that the term relates to a substrate of the MAP kinase. The technical feature associated with the term **conservatively substituted** is unclear since the term does not have an unequivocal meaning. The meaning of the term should be evident from the claim alone in the case where a specific meaning is defined elsewhere in the application.

6.3 Claims 24 and 26 refer to a product defined by a process of manufacture. This is only allowed in the case that the plant may not more precisely defined. As such the claims lack the essential technical features of the invention.